REMARKS

This amendment is in response to the Office Action, dated July 15, 2004 ("Office Action"). Following entry of the present amendment, claims 12-22 are pending. Claims 12-16, 18-20 and 22 have been amended. No new matter has been added. Reconsideration and allowance of the claims in view of the foregoing amendment and ensuing remarks are respectfully requested.

The specification has been amended to include reference to the amino acid sequences presented in the enclosed "Sequence Listing." The Sequence Listing is submitted herewith both in computer readable form (CRF) and in hard copy, along with the required Statement. Entry of the Sequence Listing into the present application is respectfully requested. Support for this Sequence Listing may be found in the specification and claims as originally filed; in particular, in the carryover paragraph beginning at page 4, and in claim 14 as originally presented.

Claim 12 has been amended to more particularly point out that which Applicants regard as their invention. Claim 12, as amended, describes a "method of detecting a rodent infestation" including *"taking a sample . . . performing an assay . . . and detecting a rodent infestation."* Support for this amendment may be found throughout the specification and claims as originally presented; for example, at page 6, line 1 through page 8, line 16.

Claim 14 has been amended to more particularly point out that which Applicants regard as their invention. As amended, claim 14 describes various major urinary proteins by SEQ ID NOs, in accordance with alternate embodiments of the invention. Support for this amendment may be found throughout the specification and claims as originally filed; for example at page 4, line 29 through page 5, line 5.

Claims 13, 15, 19 and 20 have been amended to provide proper antecedent basis with respect to the singular protein described in the independent claim from which they depend, and to include the verb "is" for grammatical purposes.

Claims 16 and 18 have been amended to more clearly describe the steps in the inventive method to which these claims incorporate additional features.

Claim 22 has been amended to delete reference to a "tile or sheet."

In the Office Action, Examiner rejected claims 12-22 under 35 U.S.C. § 112, second paragraph, *"as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."* Specifically, Examiner indicated that claims 12-15 omitted essential steps, because *"[c]laim 1 recites a method for detecting the presence of urinary proteins from rodents on a surface, but the method does not include essential steps such as contact, binding and detection."* Further, Examiner indicated that, in claim 14, *"the limitation 'and functional derivatives thereof' is vague because it is unclear as to what is encompassed by this term."* Examiner also indicated that Applicants' use of Genbank accession numbers in claim 14 was unacceptable and required a sequence listing. This rejection is respectfully traversed.

As amended, claim 12 includes a clear recitation of the inventive methodology. Specifically, claim 12 describes *"taking a sample from a surface. . . performing an assay . . . and detecting a rodent infestation based upon the presence of the urinary protein detected in the sample."* It is respectfully submitted that claim 12, as amended, properly interrelates the essential elements of Applicants' invention as defined in the specification. *See* MPEP § 2172.01.

Additionally, claim 14, as amended, no longer includes the term "and functional derivatives thereof." Also, Applicants enclose herewith a Sequence Listing, both in computer readable form (CRF) and in hard copy, listing the amino acid sequences that had previously been referred to in the specification and claims by Genbank accession numbers. Moreover, Applicants' claim 14 has been amended to refer to these sequences by the SEQ ID NOs that correspond to those in the Sequence Listing. Applicants have also amended the specification to include these SEQ ID NOs.

In light of the aforementioned remarks and amendments to the claims and specification, Applicants respectfully submit that claims 12-22 are sufficiently definite, and therefore respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

In the Office Action, Examiner rejected claim 14 under 35 U.S.C. § 112, first paragraph, indicating that *"the written description is not commensurate with the scope of the claims . . . [because n]either the claims nor the specification teach how to obtain . . . functional derivates [of the specified major urinary proteins]."* This rejection is respectfully traversed.

As noted above, Applicants' claim 14, as amended, no longer includes the term "and functional derivatives thereof." In light of this amendment, Applicants respectfully submit that claim

14 is supported by an adequate written description, and therefore respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

In the Office Action, Examiner rejected claims 12-13 and 15 under 35 U.S.C. §§ 102(a) & (e) as being anticipated by U.S. Patent No. 5,869,288 to Chapman *et al.* (hereinafter "Chapman"). In particular, Examiner found that *"[Chapman] teaches that calycins are a set of diverse protein families that contain rodent urinary proteins (mouse urinary protein, MUP, and rat alpha 2u globulin)."* Examiner further found that *"[t]hese rodent urinary proteins induce IgE antibody responses as they become airborne when deposited on particles in laboratory animal rooms or houses containing rats"* (internal citations omitted). This rejection is respectfully traversed.

A claim is anticipated *"only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."* *See* MPEP § 2131 (citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Chapman describes various cockroach allergens, and their ability to induce IgE binding. *See, e.g.,* Col. 1, lines 11-22. The reference teaches that this binding may generate an allergic or asthmatic reaction in sensitive individuals. Id. Chapman also notes that particular rodent urinary proteins can become airborne in a manner similar to the cockroach allergens described therein, and that these rodent urinary proteins may therefore cause a similar allergic or asthmatic reaction in sensitive individuals. *See* Col. 10, lines 16-24.

In sharp contrast, Applicants' invention, as claimed, relates to a method for detecting a rodent infestation by taking a sample from a surface *"upon which a urinary protein has been deposited or over which a rodent has putatively travelled or both,"* performing an assay to detect the presence of the urinary protein and detecting a rodent infestation based on having detected the urinary protein in the sample. The urinary proteins described in Applicants' specification are deposited by rodents that run loose in a house or other building, such as a hospital; for instance, in the course of marking their territory. *See, e.g.,* page 2, line 23 through page 3, line 7. In other words, these urinary proteins are typically deposited by rodents as they physically travel about the premises, and not by way of airborne diffusion.

Chapman does not describe Applicants' methodology. In fact, Chapman does not describe a method for detecting a rodent infestation. Rather, Chapman is limited to the identification of various

cockroach allergens, and the discussion of the ability of those allergens as well as allergens from other animals to induce an allergic or asthmatic response in sensitive individuals. Even with respect to the allergens to which this reference primarily relates (*i.e.*, cockroach allergens), Chapman does not describe the use of these compounds in detecting an infestation -- of cockroaches, rodents or other animals.

In light of the foregoing remarks, Applicants respectfully submit that claims 12-13 and 15 are not anticipated by Chapman, and therefore respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §§ 102 (a) & (e).

In the Office Action, Examiner rejected claim 14 under 35 U.S.C. § 103(a) as being rendered obvious by Chapman in view of Robertson et al. (J. BIOL. CHEM., 316:265-272 (1996); hereinafter "Robertson"). Specifically, Examiner found that Chapman *"is silent with respect to the amino acid sequence of major urinary proteins as defined by Genbank Accession Numbers."* However, Examiner continued, *"[Robertson] discloses a table that includes a proposed classification and nomenclature for uMUPs that are listed by their Genbank accession numbers X00907, M16355, M16356, and X00908."* Therefore, Examiner concluded, *"it would have been obvious . . . to modify the teachings of [Chapman] to include the identification of major urinary proteins by their amino acid sequences to distinguish them from one another."* This rejection is respectfully traversed.

A *prima facie* showing of obviousness requires a *"suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings . . . there must be a reasonable expectation of success . . . [and] the prior art reference[s] . . . must teach or suggest all the claim limitations."* *See* MPEP § 2142 (emphasis added). Additionally, *"[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure"* (emphasis added). Id. *"The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the claimed combination"* (emphasis in original). MPEP § 2143.01. Finally, a conclusion of obviousness may not be predicated on hindsight; instead it can only be based upon *"the knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned from applicant's disclosure"*

(emphasis added). *See* MPEP § 2145(X)(A) (citing *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971)).

As discussed above, Chapman does not anticipate Applicants' invention, as claimed, because, *inter alia*, Chapman does not describe the detection of a rodent infestation by assaying for a urinary protein on a surface. Assuming, *arguendo*, that Chapman may be properly combined with Robertson to predicate an obviousness rejection, which Applicants in no way concede, this combination of references does not render obvious Applicants' claimed method; specifically, it does not teach, disclose or suggest the assaying of urinary proteins to detect a rodent infestation.

Applicants do not suggest that the urinary proteins identified by the Genbank accession numbers in their specification are novel; indeed, Applicants note that these particular urinary proteins are *"[e]xamples of known MUP amino acid sequences."* *See* page 5, lines 2-3. Rather, it is the use of these urinary proteins in Applicants' inventive method that is claimed, and which is not taught, suggested or described in Chapman in view of Robertson. In fact, the first suggestion of the use of these proteins for detection of a rodent infestation is found in Applicants' disclosure, and not in the prior art.

In light of the foregoing remarks, Applicants respectfully submit that claim 14 is not rendered obvious by Chapman in view of Robertson, and therefore respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

In the Office Action, Examiner rejected claims 16-17 under 35 U.S.C. § 103(a) as being rendered obvious by Chapman in view of Bayard *et al.* (ELECTROPHORESIS, 189:1642-1648 (1998); hereinafter "Bayard"). In particular, Examiner found that Chapman does not teach *"an immunoassay system associated with a double antibody system."* However, Examiner found that *"[Bayard] teaches rat urinary proteins binding human IgE antibodies . . . [as well as] the affinity and specificity of IgE antibodies utilizing a double antibody system, particularly a dot blot with concentrated rat urine"* (internal citations omitted). Further, Examiner noted, *"Bayard discloses detection of IgE rat antigens with anti-IgE (secondary antibodies) antibodies are important because low detection signals could be the result of IgE antibodies (primary antibodies) that can be lost during washing of the membrane due to weak binding"* (internal citations omitted). Therefore, Examiner concluded, *"it would have been obvious . . . to modify the reference of [Chapman] to*

include a double antibody system to detect the degree of affinity of the IgE antibodies to rat urinary proteins." Examiner also noted that *"a double antibody system is well known in the art of its detection sensitivity."* This rejection is respectfully traversed.

As discussed above, Chapman does not anticipate Applicants' invention, as claimed, because, *inter alia*, Chapman does not describe the detection of a rodent infestation by assaying for a urinary protein on a surface. Assuming, *arguendo*, that Chapman may be properly combined with Bayard to predicate an obviousness rejection, which Applicants also in no way concede, this combination of references does not render obvious Applicants' claimed method; specifically, it does not teach, disclose or suggest the assaying of urinary proteins to detect a rodent infestation.

Applicants do not suggest that a double antibody system is itself novel. Indeed, Applicants recognize the availability of various commercial enzyme-linked secondary antibodies that may be employed in connection with their inventive methodology. *See* page 6, line 30 through page 7, line 2. Rather, it is the use of a double antibody system in connection with Applicants' inventive methodology that is claimed, and which is not taught, suggested or described in Chapman in view of Bayard. In fact, the first suggestion of the use of a double antibody system for detection of a rodent infestation with urinary proteins is found in Applicants' disclosure, and not in the prior art.

In light of the foregoing remarks, Applicants respectfully submit that claims 16-17 are not rendered obvious by Chapman in view of Bayard, and therefore respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

In the Office Action, Examiner rejected claims 18-22 under 35 U.S.C. § 103(a) as being rendered obvious by Chapman in view of Bayard and further in view of U.S. Patent No. 5,359,960 to Yamanton. Examiner found that Chapman in view of Bayard does not teach a system to collect urine samples, but that Yamanton *"teaches a diagnostic system for use with small animals consisting of using plastic liners (sheets or substratum) to collect urine from animal deposits . . . [and that t]he urine sample is transferred to a dipstick (swab) for testing of the analyte"* (internal citations omitted). Therefore, Examiner concluded, *"it would have been obvious . . . to modify the teachings of [Chapman] in view of [Bayard] to utilize a urine collection system taught by Yamanton . . . to provide simple home testing of animals without the use of a laboratory and the need of trained technicians."* Examiner further noted that nitrocellulose is a *"well known material in the art used*

for sample collection." This rejection is respectfully traversed.

As discussed above, Chapman does not anticipate Applicants' invention, as claimed, because, *inter alia*, Chapman does not describe the detection of a rodent infestation by assaying for a urinary protein on a surface. Similarly, Chapman in view of Bayard does not render obvious Applicants' claimed method. Thus assuming, *arguendo*, that Chapman may be properly combined with both Bayard and Yamanton to predicate an obviousness rejection, which Applicants in no way concede, this combination of references does not render obvious Applicants' claimed method; specifically, it does not teach, disclose or suggest the assaying of urinary proteins to detect a rodent infestation.

Applicants do not suggest that using plastic sheets and swabs is itself a novel means for collecting samples from an animal. Rather, it is the collection of samples from *"a surface upon which a urinary protein has been deposited or over which a rodent has putatively travelled or both"* and the subsequent assaying of the sample and detection of an infestation that is claimed, and which is not taught, suggested or described in Chapman in view of Bayard in further view of Yamanton. The first suggestion of this methodology for detection of a rodent infestation with urinary proteins is found in Applicants' disclosure, and not in the prior art.

In light of the foregoing remarks, Applicants respectfully submit that claims 18-22 are not rendered obvious by Chapman in view of Bayard in further view of Yamanton, and therefore respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

Applicants believe that the present amendment and foregoing remarks place the application in condition for allowance. A favorable action is respectfully requested. If for any reason Examiner finds the application other than in condition for allowance, Examiner is requested to call the

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undersigned attorney at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,
PILLSBURY WINTHROP LLP

Date: September 28, 2004

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